

### Remarks

This Amendment is being filed concurrently with a Request for Continued Examination ("RCE"). Reconsideration and allowance of this application, as amended, are respectfully requested.

Claims 1 and 18 have been amended to even more particularly define the various embodiments of the present invention. Claims 1, 2, and 4-22 remain pending herein, with claims 12-15 withdrawn from consideration as directed to a non-elected invention. Claims 1, 18, and 21 are independent. The rejections are respectfully submitted to be obviated in view of the remarks presented herein.

Applicant again acknowledges with gratitude the allowance of claim 21 and the indication of allowable subject matter in claims 5, 9, and 16. However, for at least the reasons presented below, Applicant again submits that all of the claims presently under consideration are allowable.

#### 35 U.S.C. § 103(a) - Abel and Laffay

Claims 1, 2, 6, 7, 10, 11, and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,265,760 to Abel et al. (hereinafter "Abel") in view of FR 2,766,797 to Laffay et al. ("Laffay").

The Office Action acknowledges in pertinent part that Abel "does not specifically teach that the filter means of the inner sheet is disposed exclusively at the distal end of the bag

(i.e. opposite side from the inlet)" (Office Action page 4, numbered paragraph 1). Nonetheless, the Office Action asserts that "it has been held that the omission of an element and its function is obvious when the function of the element is not desired." The Office Action concludes that "it would have been obvious to reconfigure the inner sheet of Abel such that the filter means is only disposed at the distal end of the chamber if transfer of fluid from the first chamber to the second chamber was only desired at the distal end of the device."

The rejection of claims 1, 2, 6, 7, 10, 11, and 22 under § 103(a) based on Abel and Laffay is respectfully deemed to be obviated. For at least the following reasons, the combined disclosures of Abel and Laffay would not have rendered obvious Applicant's presently claimed invention.

The Office Action seems to acknowledge that Applicant's claimed invention differs from Abel's device at least by having (i) an inner sheet having a screen portion located only at the distal end thereof, and (ii) one bushing having a first and second opening providing communication with a solvent inlet line and a solution discharge, respectively.

However, the logic that is employed in two different sections of the Office Action seems to be internally inconsistent. That is, it appears as though the examiner has used two different lines of argument, i.e., a first line of argument in the claim rejections section (Office Action page 4, paragraph 2), and a

second, different line of argument in the "Response to Arguments" section (Office Action page 2).

According to the first line of argument, the reconfiguration of the inner sheet of the Abel device is allegedly obvious. That is, "it would have been obvious to reconfigure the inner sheet of Abel such that the filter means is only disposed at the distal end of the chamber if transfer of fluid from the first chamber to the second chamber was only desired at the distal end of the device" (Office Action page 4).

However, nowhere in the Abel patent is it stated or even implied that a "transfer of fluid from the first chamber to the second chamber was only desired at the distal end of the device." In fact, Abel's horizontal configuration strongly suggests that transfer of fluid is desired to the same extent in any of the regions of the absolute filter, and thus implicitly teaches away from preferring a particular region of the absolute filter over another region. Therefore, Applicant respectfully submits that the first line of argument employed in the Office Action is contradictory to the horizontal configuration of the Abel device.

The second line of argument (in the "Response to Arguments" section) addresses Applicant's advantageous effect of avoiding a shortcut of fluid between the first and the second chambers. The Office Action alleges that the problem of fluid shortcut would not arise in the Abel device. This second line of argument obviously requires a horizontal configuration of the Abel

device. That is, the Office Action states that "in Abel's figure 5A, the chamber is oriented such that the filter is disposed horizontally, such that the powdered solute contacts substantially the entire filter" (Office Action page 2).

In summary, the two lines of argument employed in the Office Action seem to be contradictory. That is, if Abel *requires* "the powdered solute [to contact] substantially the entire filter," then how "would [it] have been obvious to reconfigure the inner sheet of Abel such that the filter means is only disposed at the distal end of the chamber"?

Nevertheless, to advance prosecution, claim 1 has been amended so as to even more particularly define the structural features of the bicompartiment bag. Instant claim 1 requires, *inter alia*, that the "flexible inner sheet [be] oriented vertically relative to a top portion and a bottom portion of the bag." See, e.g., Figure 8 ("a side view of the bag for haemodialysis machines of the present invention" per specification page 7).

One distinguishing feature of the instant invention is the claimed flexible inner sheet that has the "screen portion located only at a distal end thereof at the bottom portion of the bag." That is, *when the flexible inner sheet is oriented vertically relative to the top and bottom of the bag*, the sheet and screen portion prevent solvent entering the inlet from "shortcutting" the path to the outlet. See the arguments presented at pages 13-14 of Applicant's Amendment filed September 3, 2009.

The combined disclosures of Abel and Laffay simply do not teach all of Applicant's claim features. More specifically, the asserted Abel/Laffay combination fails to teach, *inter alia*, Applicant's claimed "flexible inner sheet oriented vertically relative to a top portion and a bottom portion of the bag, the inner sheet dividing an interior of the bag into a first chamber that is at least partially filled with a powdered solute and a second chamber and that has a screen portion located only at a distal end thereof at the bottom portion of the bag."

As indicated above in the introductory remarks, the Office Action acknowledges that Abel "does not specifically teach that the filter means of the inner sheet is disposed exclusively at the distal end of the bag (i.e. opposite side from the inlet)." But, the difference between Abel's device and Applicant's claimed bicompartiment bag is much more than that which the examiner concedes. Not only does Abel "not specifically teach that the filter means of the inner sheet is disposed exclusively at the distal end of the bag," but instead in fact teaches that the "absolute filter 105" extends across the entire width of flexible bag 101. See Abel's Figure 5, which clearly illustrates the aforementioned point. That is, Abel discloses that "[t]he interior of the container 101 is divided into an inlet compartment 106 and an outlet compartment 107 by an absolute filter 105" (Abel column

3, lines 36-38) (emphasis added). Abel's filter 105 is continuous, and extends across the entire width of the bag 101.

If, with Applicant's claimed bicompartiment bag, where both the solvent inlet and the solution outlet are in close proximity to each other, one were to employ Abel's filter, there is the possibility that solvent entering the inlet would simply "shortcut" the path to the outlet. To avoid the aforementioned shortcut is precisely why Applicant's claimed invention includes the feature of the special inner filter layer 7, which is "oriented vertically relative to a top portion and a bottom portion of the bag," having the screen portion *only at the distal end*, i.e., opposite from the adjacent inlet and outlet.

And, Applicant respectfully submits that the Office Action's stated rationale for disregarding the above-described deficiency of Abel represents an *impermissible* hindsight reconstruction. Applicant can discover no disclosure in Abel or elsewhere to support the examiner's contention that "it would have been obvious to reconfigure the inner sheet of Abel such that the filter means is only disposed at the distal end of the chamber if transfer of fluid from the first chamber to the second chamber was only desired at the distal end of the device." In Abel's device, the absolute filter 105 only serves the function of filtering the fluid moving from inlet compartment 106 to outlet compartment 107. In fact, with regard to movement of the fluid and filtering, Abel simply teaches that "the water diluent is introduced through the

inlet means to effect dilution of the chemicals in inlet compartment 106, with the diluent contacting the adsorbent and *flowing through the absolute filter 105 into the outlet compartment 107* for delivering the chemicals in diluted form for in vivo use through outlet means 103." Abel is completely silent, however, about anything related to *the stability of the concentration of the dissolved solid* in the fluid exiting the bag outlet.

However, an important aspect of Applicant's invention is *in fact the stability of the concentration of the dissolved solid in the fluid exiting the outlet*. See, for example, the objects of this invention described in the very first two paragraphs of the instant specification. For example, Applicant discloses that one object is to avoid using the conventional tubing that is employed "to preclude the dissolving powder from migrating out of the device before it is dissolved" (specification page 1, lines 15-16). To avoid the shortcut that could result from using the filter of Abel, and consequently, the associated migration of undissolved powder from the bag, is precisely why Applicant's claimed invention includes the feature of the special inner filter layer 7, which is "oriented vertically relative to a top portion and a bottom portion of the bag," having the screen portion *only at the distal end*, i.e., at the end of the bag opposite from the inlet and outlet.

Furthermore, regardless of what Laffay may disclose with regard to a "bushing 8," the disclosure of Laffay does not rectify any of the above-described structural deficiencies of Abel.

Finally, there is simply no teaching in either Abel or Laffay that would have led one to select the references and combine them in a way that would produce the invention defined by any of Applicant's pending claims. Laffay discloses a package that is "applicable to packaging acid substances for a dialysis" (English-language abstract).

Furthermore, Abel's device is structurally different from Laffay's packaging at least by Abel's horizontal orientation in contrast to Laffay's vertical orientation, by the use of separate inlets and outlets versus a connector combining those functions, and by the absence versus the presence of tubes.

There is simply no teaching in either of the references that a person having ordinary skill in the art would try to improve the bag of Laffay by using the bag of Abel in order to avoid using the outlet tubing of Laffay, yet while still employing Laffay's bushing.

And finally, even if the person having ordinary skill in the art were to combine the disclosures of Abel and Laffay, the result would not be a bag having "a flexible inner sheet oriented vertically relative to a top portion and a bottom portion of the bag, the inner sheet dividing an interior of the bag into a first chamber that is at least partially filled with a powdered solute

and a second chamber and that has a screen portion located only at a distal end thereof at the bottom portion of the bag," as required by present independent claim 1.

Therefore, the combined disclosures of Abel and Laffay would not have rendered obvious the invention defined by instant claim 1. Claims 2, 6, 7, 10, 11, and 22 are allowable because they depend from claim 1, and for the subject matter recited therein.

35 U.S.C. § 103(a)

Claims 4 and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Abel in view of Laffay, and further in view of U.S. Patent No. 5,616,305 to Mathieu. Claims 8 and 17-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Abel in view of Laffay, and further in view of U.S. Patent Application Pub. No. 2002/0030002 of Verkaart et al. ("Verkaart").

Each of the aforementioned rejections under § 103(a) is also respectfully deemed to be obviated. Claims 4 and 10, and claims 8 and 17, all depend, either directly or indirectly, from claim 1. Claim 1 is allowable for at least the reasons explained above. The disclosures of Mathieu and Verkaart add nothing that would rectify any of the above-described deficiencies of the asserted Abel/Laffay combination. More specifically, the disclosures of Mathieu and Verkaart are irrelevant for the reasons articulated in Applicant's replies filed October 26, 2007, December 7, 2007, June 24, 2008, and December 16, 2008. Accordingly, claims

4, 8, 10, and 17 are allowable because they depend from claim 1, and for the subject matter recited therein.


Independent claim 18 is similarly allowable. Instant claim 18 requires, *inter alia*, that "the first inner sheet [be] oriented vertically relative to a top portion and a bottom portion of the bag."

Claim 18 is therefore allowable for at least reasons similar to those explained above with respect to claim 1. Verkaart's disclosure of a "tube sealing means" adds nothing that would rectify any of the above-described deficiencies of the asserted Abel/Laffay combination. Claims 19 and 20 are allowable because they depend from claim 18, and for the subject matter recited therein.

In view of the foregoing, this application is now in condition for allowance. If the examiner believes that another interview might expedite prosecution, the examiner is invited to contact the undersigned.

Respectfully submitted,

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